Any correspondence regarding this publication should be sent to the publisher, American Society of Health-
System Pharmacists, 4500 East West Highway, Suite 900, Bethesda, MD 20814, attention: Special Publishing.

The information presented herein reflects the opinions of the contributors and advisors. It should not be inter-
preted as an official policy of ASHP or as an endorsement of any product.

Because of ongoing research and improvements in technology, the information and its applications contained
in this text are constantly evolving and are subject to the professional judgment and interpretation of the prac-
titioner due to the uniqueness of a clinical situation. The editors and ASHP have made reasonable efforts to
ensure the accuracy and appropriateness of the information presented in this document. However, any user
of this information is advised that the editors and ASHP are not responsible for the continued currency of the
information, for any errors or omissions, and/or for any consequences arising from the use of the information
in the document in any and all practice settings. Any reader of this document is cautioned that ASHP makes
no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the
information contained in this document and specifically disclaims any liability to any party for the accuracy
and/or completeness of the material or for any damages arising out of the use or non-use of any of the infor-
mation contained in this document.

Acquisitions Editor: Daniel Cobaugh

Editorial Project Manager, Special Publishing: Ruth Bloom

Production Manager: Johnna Hershey

Cover & Page Design: David Wade

Library of Congress Cataloging-in-Publication Data
Names: Wilson, Andrew L., editor. | American Society of Health-System
Pharmacists, issuing body.
Title: The 340B program handbook : integrating 340B into the health-system
Description: Bethesda, MD : American Society of Health-System Pharmacists,
[2018] | Includes bibliographical references and index.
Identifiers: LCCN 2018003699 | ISBN 9781585285983 (pbk.)
Subjects: | MESH: Pharmaceutical Services--economics | Government Programs |
Economics, Pharmaceutical | Health Plan Implementation | United States
Classification: LCC RS100 | NLM QV 736 AA1 | DDC 362.17/82--dc23 LC record available at https://lccn.
loc.gov/2018003699

© 2018, American Society of Health-System Pharmacists, Inc. All rights reserved.

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or
mechanical, including photocopying, microfilming, and recording, or by any information storage and retrieval
system, without written permission from the American Society of Health-System Pharmacists.

ASHP is a service mark of the American Society of Health-System Pharmacists, Inc.; registered in the U.S.
Patent and Trademark Office.

Printed in Canada.

ISBN: 978-1-58528-598-3

10 9 8 7 6 5 4 3 2 1
The 340B Handbook

is dedicated

to my wife Janet

for her support through this
and the many professional
projects in our life together.
# Table of Contents

Preface ................................................................................................................................. vii
Contributors ........................................................................................................................ ix
Acknowledgments ............................................................................................................... xi

1. Introduction to the 340B Program: Current Perspectives ............................................. 1  
   Andrew L. Wilson, PharmD, FASHP

2. A Historical Perspective on the 340B Program’s Purpose ............................................. 7  
   William von Oehsen, JD

3. 340B Program Requirements and Compliance Issues .................................................. 17  
   William von Oehsen, JD, Barbara Straub Williams, JD and Shuchi Parikh, JD

4. The Basics of 340B Program Implementation ................................................................ 37  
   Christopher S. Shain, PharmD, BCPS and Douglas J. Hosie, MBA, RPh

5. Operations and Business Considerations in Implementing and Optimizing 340B Software: 340B Considerations in the Mixed-Use Pharmacy ........................................ 53  
   Christopher S. Shain, PharmD, BCPS and Gregg Niemiec, BS, RPh

6. 340B Pharmacy Supply Chain ....................................................................................... 67  
   Lisa N. Schatz, PharmD, BCPS and Steven Sundberg, PharmD

7. 340B Policies and Procedures ....................................................................................... 87  
   Lisa N. Schatz, PharmD, BCPS and Fern Paul-Aviles, PharmD, MS, BCPS

8. 340B Considerations in Retail and Specialty Pharmacy ................................................ 107  
   Kevin A. Scheckelhoff, MBA, RPh and Heather Easterling, MBA, PharmD

9. Business and Supply Chain Considerations in 340B Contract Pharmacy ..................... 125  
   Julie Houston, CPhT and Andrew L. Wilson, PharmD, FASHP

10. Chargebacks under 340B Constraints ......................................................................... 139  
    Katheryne Richardson, PharmD and Christopher Hatwig, MS, RPh, FASHP

11. 340B Considerations for Rural Hospitals ..................................................................... 151  
    Charles Cooper, MBA, RPh and Madeline Carpinelli Wallack, PhD, MS

12. 340B Implementation and Operations Considerations for Free-standing Cancer Centers .................................................................................................................................................. 161  
    Krist Azizian, PharmD; John P. Gray, PharmD, MS, BCPS; and Kim Le, PharmD

13. Developing a High-Performing 340B Program .............................................................. 173  
    Gregg Niemiec, BS, RPh and Andrew L. Wilson, PharmD, FASHP

14. Financial Management in the 340B Program ................................................................ 197  
    Andrew L. Wilson, PharmD, FASHP
Table of Contents

15. Preparing for and Surviving a HRSA Audit ............................................................... 203
    Kavish Choudhary, PharmD, MS; Lauren Meekins, PharmD, MS, BCPS; and William Black, MBA, PharmD, MS, BCPS

16. Manufacturer Considerations and Perspectives on the 340B Program ............... 225
    Marcus Farbstein, MBA, RPh

17. Future-proofing Your 340B Program .................................................................... 241
    Andrew L. Wilson, PharmD, FASHP

Index ............................................................................................................................ 247
The 340B program remains among the most significant supply chain savings opportunities for eligible nonprofit hospitals and government grantee clinics. Nearly 45% of U.S. hospitals participate in the 340B program ranging from small rural hospitals to the largest academic medical centers (AMCs) and integrated delivery networks (IDNs). The regulatory boundaries and operational requirements present a significant challenge to achieve results and mitigate risk. An active 340B program engages a broad spectrum of institutional resources in pharmacy, finance, compliance, and information technology, among others. The goal of community benefit for the care for the uninsured, underinsured, and low-income patients can be well-served through 340B program participation results.

Key elements of the 340B program are not fully outlined in law and regulation. Due to constraints on government oversight authority, formal regulatory guidance exists in only a few areas of the program. 340B program oversight by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) is supported through guidance documents, frequently asked questions (FAQs) posted on HRSA and Apexus web sites, a call center, and structured training programs through Apexus, the 340B Prime Vendor.

OPA fosters a view of compliance through on-site and desk audits with the primary result of program alignment across covered entities on key policy issues and compliance activities. The primary consequences of audit findings result in posting of violations on the HRSA web site and repayment of unearned 340B discount to manufacturers. OPA, Apexus, 340B Health, and numerous established and independent consultants provide support to 340B program participants, primarily by offering compliance-focused and policy-based solutions.

Pharmacy leaders in 340B hospitals experience a strong tension between meeting detailed and complex 340B compliance requirements as well as supporting technical supply chain efficiency and effectiveness goals, including drug shortages and achieving health-system financial objectives. Drug shortages, formulary changes, supply chain efficiency, and other operating concerns are amplified and complicated by 340B. In addition to health-system operations challenges, the complexities of pharmacy regulation, including state board and Drug Enforcement Administration (DEA) requirements and the requirements of the Drug Supply Chain Security Act (DSCSA), must also be considered.

The 340B Program Handbook is designed as a practical guide for pharmacy leaders, hospital administrators, business managers, and pharmacy supply chain professionals implementing, maintaining, or overseeing a high-performing 340B program. The 340B Handbook content focuses on financial, business, and supply chain performance constraints and opportunities in the face of unique 340B options and compliance constraints.

The Handbook is designed to offer well-organized, practical information that considers and integrates 340B into the current care delivery model, information systems, and the increasingly complex healthcare supply chain beyond 340B. In seeking 340B advice, hospitals generally engage “340B experts” and receive guidance that honors 340B program requirements. In contrast, the Handbook assembles a group of professionals who work with 340B every day to provide a framework for building and managing an effective contemporary supply chain that integrates 340B program requirements.

ASHP members in pharmacy leadership positions (vice presidents, directors of pharmacy, assistant directors of pharmacy), pharmacy business managers, supply chain leaders, and health-
Preface

system compliance officers outside pharmacy should find the Handbook to be a practical guide to implementing 340B and as a support in managing leadership conversations regarding 340B program expectations.

Andrew L. Wilson, PharmD, FASHP

REFERENCES


Contributors

CONTRIBUTING EDITOR
Andrew L. Wilson, PharmD, FASHP
Vice President, 340B Solutions
McKesson U.S. Pharmaceutical
Richmond, Virginia

CONTRIBUTORS

Krist Azizian, PharmD
Chief Pharmacy Officer
USC Norris Cancer Hospital, Keck Hospital of USC
University of Southern California
Los Angeles, California

William Black, MBA, PharmD, MS, BCPS
Pharmacy Operations Manager
University of Utah
Salt Lake City, Utah

Kavish Choudhary, PharmD, MS
Senior Director
Inpatient and Infusion Pharmacy Services
University of Utah Health
Salt Lake City, Utah

Charles Cooper, MBA, RPh
340B Program Director
Fairview Pharmacy Services
Minneapolis, Minnesota

Heather Easterling, MBA, PharmD
Director, Pharmacy Services
Medical University of South Carolina
Charleston, South Carolina

Marcus Farbstein, MBA, RPh
Director, Public Policy & Government Markets
Medivation
613 Langston Lane
Falls Church, Virginia

John P. Gray, PharmD, MS, BCPS
Medication Safety Officer
Keck Medical Center of USC
University of Southern California
Los Angeles, California

Christopher Hatwig, MS, RPh, FASHP
President
Apexus
Irving, Texas

Douglas J. Hosie, MBA, RPh
System Director of Pharmacy
Rochester Regional Health
Rochester, New York

Julie Houston, CPhT
Senior Director, Retail 340B Solutions
McKesson U.S. Pharmaceutical
Boise, Idaho

Kim Le, PharmD*
Director
Health System Value and Outcomes
Tesaro, Inc.
Los Angeles, California

Lauren Meekins, PharmD, MS, BCPS
Clinical Manager
UNC Shared Services Center Pharmacy
University of North Carolina at Chapel Hill
Raleigh, North Carolina

*At the time that Chapter 12 was written, Dr. Le was Director of Pharmacy and Investigational Drug Services at USC Norris Cancer Hospital.
Contributors

**Gregg Niemiec, BS, RPh**  
*Managing Consultant, 340B Solutions*  
McKesson U.S. Pharmaceutical  
San Antonio, Texas

**Shuchi Parikh, JD**  
*Associate*  
Powers, Pyles, Sutter & Verville  
Washington, DC

**Fern Paul-Aviles, PharmD, MS, BCPS**  
*Director, 340B and Regulatory Program Compliance*  
Carolinas Healthcare System  
Charlotte, North Carolina

**Katheryne Richardson, PharmD**  
*Vice President*  
Apexus  
Virginia Beach, Virginia

**Lisa N. Schatz, PharmD, BCPS**  
*Managing Consultant, 340B Solutions*  
McKesson U.S. Pharmaceutical  
Wilmington, North Carolina

**Christopher S. Shain, PharmD, BCPS**  
*Assistant Vice President, 340B Solutions*  
McKesson U.S. Pharmaceutical  
Fenton, Missouri

**Steven Sundberg, PharmD**  
*Director of Pharmacy*  
Advocate Healthcare Pharmacy Central Supply Center  
Algonquin, Illinois

**William von Oehsen, JD**  
*Principal*  
Powers, Pyles, Sutter & Verville  
Washington, DC

**Madeline Carpinelli Wallack, PhD, MS**  
*Principal*  
RxX Consultants  
Minneapolis, Minnesota

**Barbara Straub Williams, JD**  
*Principal*  
Powers, Pyles, Sutter & Verville  
Washington, DC
I would like to acknowledge the support of my McKesson colleagues—those who contributed to this volume and those who support the supply cad service chain for the many hospitals and clinics that engage in the 340B program.

I would also like to acknowledge the insight and continued focus of the Apexus leadership team and 340B University colleagues in building and communicating with the community of 340B program stakeholders. Thanks to the current and past leadership of the HRSA Office of Pharmacy Affairs; 340B Health along with friends, colleagues, customers, and clients in covered entities; group purchasing operations; manufacturers; 340B administrators; and consultants.

Andrew L. Wilson
April 2018